

DRY EYE DISEASE AND PERFLUOROHEXYLOCTANE AS A TREATMENT OPTION

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Topic Overview

More than 16 million people in the United States have dry eye disease. Effective treatments are needed to provide relief to these patients. In 2023, the Food and Drug Administration approved perfluorohexyloctane to treat dry eye disease. Perfluorohexyloctane is a semifluorinated alkane indicated for treating the signs and symptoms of dry eye disease (DED). Its exact mechanism of action is unknown, but it forms a monolayer in the tear film to reduce evaporation. Clinicians may review the treatment options, the risk-benefit profiles of treatment options, and a patient's medical history of dry eye disease. Following this review, the clinician and patient may consider whether perfluorohexyloctane can improve the patient's outcomes.

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Target Audience: This educational activity is for pharmacists.

How to Earn Credit: From August 23, 2023, through August 23, 2026, participants must:

- 1) Read the “learning objectives” and “author and planning team disclosures;”
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Learning Objectives: Upon completion of this educational activity, participants should be able to:

1. **Define** dry eye disease and its diverse clinical presentations
2. **Describe** the causes of dry eye disease
3. **Compare** the management of mild dry eye disease symptoms to the management of severe symptoms
4. **Explain** the resulting action of perflurohexyloctane

Disclosures

The following individuals were involved in developing this activity: Steven Malen, PharmD, MBA, and Pamela Sardo, PharmD, BS. Pamela Sardo was an employee of Rhythm Pharmaceuticals until March 2022 and has no conflicts of interest or relationships regarding the subject matter discussed. There are no financial relationships relevant to this activity to report or disclose by any of the individuals involved in the development of this activity.

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Introduction

Millions of Americans suffer from a condition known as dry eye disease (DED). Dry eye disease causes discomfort and dryness of the ocular surface. The symptoms of dry eye disease are managed based on the severity of the case. Dry eye disease may present as mild, moderate, or severe. Currently, it can be managed but not cured. Perfluorohexyloctane may be an effective option in managing DED.

Defining Dry Eye Disease

Dry eye disease is a disease of the eye's surface.^{1,2} Dry eye disease is called by other names, such as keratoconjunctivitis sicca, sicca syndrome, keratitis sicca, dry eye syndrome, xerophthalmia, dysfunctional tear syndrome, and ocular surface disease. Additionally, Sjögren's syndrome is a form of DED where the eyes do not produce enough tears.³ A more expansive definition by Tsubota, *et al.* (2020) includes ocular surface epitheliopathy and neurosensory abnormalities.² These different clinical presentations have contributed to global confusion and a lack of consistency when it comes to defining and diagnosing DED.²

Dry eye disease results in ocular discomfort, visual impairment, inflammation of the ocular surface, and an unstable or deficient tear film. Some patients present with an unstable *and* deficient tear film.¹ The tear film is a thin layer of fluid that coats the eye and helps to keep it moist and healthy. When the tear film is not properly produced or distributed, it can cause symptoms such as eye dryness, irritation, and blurred vision.^{2,3}

Dry eye disease has many causes.^{1,4} Shtein, *et al.* (2016) state that DED "may be induced by a variety of different mechanisms and therefore could be thought of as a collection of diverse pathologies that lead to common symptoms of perceived ocular dryness and irritation."⁴ Its characteristics and symptoms vary greatly and lack consistency.⁴ Clinicians treating patients for DED should know that patients with no clinical evidence of dry eyes may be highly symptomatic, and patients with minimal symptoms may present with

visible damage to the ocular surface.^{1,4} This is an important consideration when evaluating a patient for DED.⁴

Meibomian gland dysfunction (MGD) is highly prevalent in DED patients and is the leading cause of *evaporative* DED.⁵ Meibomian glands express a lipid-rich secretion called meibum that is spread onto the tear film on the ocular surface with each blink. A chronic, diffuse abnormality of meibomian gland structures, terminal duct obstruction, and changes in meibum secretion characterizes MGD.⁵

New electronic technologies also create a risk for DED.^{2,6} Computer screens, smartphones, and other visual digital technologies are a part of everyday life. There is a relationship between digital screen use and DED: long periods of digital screen use can cause ocular damage and DED.⁶ This may be due to a reduced blink rate or increased incomplete blinks when looking at a digital screen, leading to ocular surface dryness.⁶

Epidemiology: Prevalence and Risk Factors for Dry Eyes

The estimates from the early 2000s state that more than 7 million people >40 years of age suffered from DED in the United States.¹ Today, the prevalence is much greater and is increasing.^{1,7} Farrand, *et al.* (2017) estimated that 16.4 million Americans have dry eye disease (DED).⁷ This number is based on data from 75,000 participants from the 2013 National Health and Wellness Survey.⁷ The study found that approximately 6.8% of the US adult population, equivalent to about 16.4 million people, have DED.⁷

Farrand, *et al.*, found that the prevalence of DED increased with age, with the highest rates observed among those aged 75 and older (18.6%).⁷ With populations in the US aging, the prevalence of DED is expected to continue rising.^{1,7}

A higher risk of DED was also found among patients aged 45-54 years compared to those aged 18-34.⁷ Gender also increases risk. Dry eye disease is higher among women (8.8%) than men (4.5%).^{7,8}

Patients having government or private insurance also had higher rates of DED diagnoses.⁷ Patients with health insurance have greater access to healthcare, so it stands to reason that diagnosis of this chronic disease would be higher among insured patients.⁷ Additionally, as mentioned above, patients with minimal symptoms may have visible damage to the ocular surface but since the symptoms are minimal, they do not seek medical care, especially if uninsured.

Within the US, there appears to be no significant difference in DED prevalence based on race, education, or geographical region.¹ However, outside the US, some studies reported a higher prevalence of DED in Asia than in Europe and North America.^{2,9} This could mean cultural or racial factors may be involved in DED etiology.²

The findings underscore the substantial impact of diagnosed DED in the US population, with notable differences by age and gender groups. It also raises questions about access to healthcare and the fact that there may be many undiagnosed cases of DED among uninsured patients.

Management of Symptoms of Dry Eyes

Dry eye disease may be managed but not cured.¹⁰ Management of DED depends on the type of symptoms, the severity of symptoms (mild, moderate, or severe), and the underlying cause of symptoms, such as inflammation of the ocular surface or ocular pain.^{1,3} For example, chronic dry eye symptoms occurring without clinical signs of dry eye may have neuropathic origins arising from central sensitization.¹

Treating the symptoms of dry eyes is challenging for two reasons. First, Saldanha, *et al.* (2017) state that current treatments for dry eyes lack strong scientific evidence.¹¹ This impacts the long-term efficacy and safety of treatment modalities. Patient outcomes are poorer because treatments may not ameliorate dry eye symptoms over the course of treatment.¹¹

Second, an accurate assessment of the causes of dry eyes is critical. If a clinical assessment is unsound, it can lead to inappropriate management or treatment decisions, which can cause greater ocular damage.²

Mild Symptoms

For mild dry eye disease, treatment usually focuses on providing relief and improving ocular lubrication.¹² Artificial tears or lubricating eye drops are commonly recommended for mild cases to help moisturize the eyes and alleviate symptoms of dryness and irritation.¹² Preservative-free formulations are preferred to minimize potential irritation from preservatives.¹²

Lifestyle modifications can help manage mild DED symptoms.^{3,12} Patients should avoid cigarette smoking, take regular breaks from digital screens, purposely blink more often when viewing digital screens, use humidifiers in dry environments, and avoid exposure to dry or windy conditions.^{3,6,12} Managing air conditioning and dry heating air may also help.³ Additionally, maintaining good eyelid hygiene and avoiding factors that exacerbate dry eye symptoms can contribute to better management of mild dry eye disease.¹²

Moderate to Severe Symptoms

In addition to the treatments and management of mild DED symptoms, moderate to severe DED can include artificial tears and lubricating eye drops remain essential for providing immediate relief.¹² For more severe cases, prescription eye drops, such as cyclosporine or lifitegrast, may be used to reduce inflammation and increase tear production.¹²

Punctal plugs or occlusion may be considered to conserve tears by blocking tear drainage. Intensive lubrication with ointments at bedtime can help reduce nighttime dryness. For underlying MGD, treatments like warm compresses, eyelid hygiene, and therapeutic eyelid massage are often recommended.^{5,12} Additionally, oral omega-3 fatty acid supplements may provide some benefits.^{5,12} In more refractory cases, autologous serum tears

or amniotic membrane transplantation may be considered. Treatment plans for moderate to severe dry eye disease should be tailored to the individual patient's specific condition and managed under the guidance of an eye care professional.¹²

In the treatment sequence for DED, several steps are taken to address the condition's varying degrees of severity. In the initial step, patient education is pivotal in conveying the strategies for managing DED. This includes imparting knowledge about dietary modifications, treatment approaches, and the anticipated prognosis.¹³ Additionally, it is essential to modify the local environment to minimize factors that exacerbate DED symptoms and to identify and possibly eliminate systemic or topical medications that might contribute to the condition.¹⁴

Moving to the next step, if the options employed in the initial stage prove insufficient, the treatment escalates.¹⁴ This involves administering non-preserved ocular lubricants to alleviate discomfort. In the presence of Demodex, if applicable, tea tree oil treatment can be considered. Overnight treatments, such as utilizing moisture chamber devices and ointments, become part of the regimen.¹⁴ Furthermore, prescription of topical medications, including antibiotics, antibiotic/steroid combinations, corticosteroids, and immunomodulatory drugs, may be warranted. Oral antibiotics like macrolides or tetracyclines could also be recommended. Techniques to conserve tears, such as punctal occlusion or moisture chamber goggles, are introduced alongside in-office therapies like intense pulsed light therapy and Meibomian gland expression.¹⁴

Should the interventions of the preceding steps fall short in delivering the desired outcomes, the approach advances to the subsequent stage. Here, treatment options broaden to incorporate oral secretagogues or autologous/allogeneic serum eye drops. Additionally, therapeutic contact lenses, including soft bandages and rigid scleral lenses, are introduced to manage the condition effectively.¹⁴

Ultimately, when the previous steps do not yield the expected results, the treatment strategy escalates further. Topical ophthalmic corticosteroids may be administered to alleviate inflammation. Prolonged use of corticosteroids; however, may lead to cataracts, increased intraocular pressure, or infection.¹⁵ Moreover, surgical interventions such as amniotic membrane grafts, surgical punctal occlusion, tarsorrhaphy, and even salivary gland transplantation might be considered to achieve the desired therapeutic outcome. By following this progressive treatment approach, patients and healthcare providers collaboratively tailor the management plan to address the unique characteristics and needs of each individual's DED condition.¹⁴

Managing Symptoms of Dry Eyes Using Perfluorohexyloctane

In 2023, the Food and Drug Administration (FDA) approved perfluorohexyloctane to treat dry eye disease. Perfluorohexyloctane is a semifluorinated alkane indicated for treating the signs and symptoms of DED.¹⁶

Clinical Trials

In two randomized, multicenter, double-masked trials (GOBI and MOJAVE) involving 1,217 patients with a history of DED and MGD, perfluorohexyloctane was evaluated for safety and efficacy.¹⁶ The patients were randomized to receive either perfluorohexyloctane or saline 0.6% four times daily for 57 days. Most patients were female, with a mean age of 57 years. The study assessed the effects of perfluorohexyloctane on both signs and symptoms of dry eye disease. The results showed that perfluorohexyloctane led to a statistically significant reduction in total corneal fluorescein staining (tCFS), indicating improved corneal health. Additionally, there was a significant reduction in visual analog scale (VAS) eye dryness scores, suggesting a relief of dry eye symptoms with perfluorohexyloctane treatment. These findings demonstrate the potential benefits of perfluorohexyloctane in managing dry eye disease and supporting its safety and efficacy in clinical trials.¹⁶

Another study aimed to assess the effectiveness and safety of perfluorohexyloctane eye drops in Chinese patients with DED associated with MGD over 57 days.¹⁷ This phase 3 clinical trial, conducted from February 2021 to September 2022, enrolled participants from 15 hospitals in China. Patients were randomly assigned to receive either perfluorohexyloctane eye drops or 0.6% sodium chloride eye drops four times daily.¹⁷ The primary outcomes were changes in total corneal fluorescein staining (tCFS) and eye dryness scores at day 57. Results showed that perfluorohexyloctane eye drops were superior to the control group regarding tCFS score and eye dryness score improvements, with significant differences observed from day 15 onwards, maintained through day 57. The treatment also alleviated other symptoms like pain, awareness of DED symptoms, and dryness frequency. Adverse events occurred in both groups but were slightly more frequent in the control group.¹⁷ The trial demonstrated the efficacy and safety of perfluorohexyloctane eye drops in managing DED associated with MGD, suggesting their potential use pending further confirmation over longer periods.¹⁷

Mechanism of Action

Perfluorohexyloctane, a type of semifluorinated alkane, consists of 6 perfluorinated carbon atoms and 8 hydrogenated carbon atoms.^{16,18} When applied to the eye, it forms a protective monolayer at the air-liquid interface of the tear film, which is expected to reduce tear evaporation. However, the precise mechanism of how perfluorohexyloctane works in the context of DED is currently unknown.¹⁶

Indications

Perfluorohexyloctane is approved for treating the signs and symptoms associated with DED.¹⁶

Dosing

To administer perfluorohexyloctane, one drop should be instilled into the affected eye(s) four times daily.¹⁶

Contraindications and Warnings

There are no contraindications for using perfluorohexyloctane.¹⁶ However, it is essential to exercise caution when using the product with contact lenses. Perfluorohexyloctane should not be applied while wearing contact lenses, and patients should remove their contact lenses before administering the eye drops. After using perfluorohexyloctane, patients should wait at least 30 minutes before reinserting their contact lenses.¹⁶

Side Effects or Adverse Events

The rates of adverse reactions observed in clinical trials for perfluorohexyloctane cannot be directly compared to those of other drugs due to varying trial conditions.¹⁶ In two randomized controlled trials involving 614 patients with DED across 68 sites in the United States, blurred vision was the most common ocular adverse reaction. Blurred vision and conjunctival redness were reported in 1-3% of individuals receiving perfluorohexyloctane.¹⁶

Drug-Drug Interactions

There are no interactions with perfluorohexyloctane.¹⁶ While there are no drug-drug interactions, there are drugs that can cause DED:¹⁴

Systemic Drugs	Topical Drugs
NSAIDs Diuretics Vasodilators Analgesics/antipyretics Antiulcer agents	Agents used to treat glaucoma Beta-blocking agents Adrenergic agonist drugs Carbonic anhydrase inhibitors Cholinergic agents

Sulfonylureas Cardiac glycosides Anxiolytics/benzodiazepines Anti-infectives Antidepressants/antipsychotics Antihypertensives Antihistamines Inhaled steroids Systemic corticosteroids Systemic hormones (women <50 yr) Hormone replacement therapy Antiandrogen therapy/medications Multivitamins	Prostaglandins Agents used to treat allergies Antiviral agents Decongestants Miotics Mydriatics and cycloplegics Preservatives Topical and local anesthetics Topical ocular NSAIDs
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Handling and Storage

Perfluorohexyloctane should be stored in a temperature range of 20°C to 25°C (68°F to 77°F). Once opened, it can be used until the expiration date on the bottle.¹⁶

Patient Counseling

Before using the eye drops, contact lenses must be removed, and they should remain out for at least 30 minutes after applying perfluorohexyloctane. To properly administer the drops, the cap should be removed from the eye drop bottle. Holding the bottle upright, gently squeeze it, then turn it upside down and release the pressure to draw air into it. With the bottle still upside down, position it above the eye and squeeze to release a drop into the eye. These steps should be repeated for the second affected eye.¹⁶

Understanding DED Management: Managing DED starts with patient education, emphasizing its chronic nature and potential progression. Recognize that ongoing treatment is essential, although results may not be immediate. Lifestyle changes are also crucial.¹⁴

Digital Device Use: If you spend extended time on digital devices, you're not alone. Many experience digital eye strain (DES) symptoms like fatigue, dryness, and headaches. Preventive strategies include preservative-free lubricating drops, blinking exercises, proper device positioning, and regular breaks. Specialized lenses might provide relief.¹⁴

Environmental Modifications: Make simple adjustments to avoid dry conditions and pollutants, like redirecting air vents, using humidifiers, and wearing sunglasses.¹⁴

Cosmetic Considerations: Review cosmetics like eye creams and makeup. Some products can worsen DED, while others, like eyelash serums and extensions, may cause discomfort.¹⁴

Diet and Hydration: Dietary changes might help, but results vary. Essential fatty acids and increased hydration could improve DED symptoms. Beware of alcohol intake, which can worsen symptoms.¹⁴

Comprehensive Treatment: Managing DED often requires multiple treatments. Understand the mechanism, goals, and duration of each. Follow a clear daily routine and consider cost and adherence challenges.¹⁴

Prescription Intervention: Inflammation might demand prescription intervention. Learn proper drop instillation. The pharmacy team can advise patients to wash their hands first and keep the eye dropper clean and not let the dropper touch the eye or other surfaces. The patient should tilt their head back and look up before squeezing the bottle. Patients may be advised to gently pull the lower eyelid down and away to hold the drop. Some medications may cause stinging or taste changes, but these are usually temporary. Initial discomfort often lessens with continued use.¹⁴

Interdisciplinary Approach and Collaboration

A recent meta-analysis involving 22 studies with a total of 2.9 million patients revealed that individuals with DED have a higher prevalence of

anxiety and depression than control groups.¹⁹ DED, a common condition affecting the tear film, leads to symptoms like ocular irritation, foreign body sensation, and visual disturbances. Interestingly, the symptoms of DED may show a correlation with non-ocular conditions such as depression and post-traumatic stress disorder (PTSD) rather than tear film parameters, suggesting a potential psychiatric aspect to the complaint.¹⁹ There is much more to learn about this interplay. These researchers believe DED and depression seem to have a bidirectional relationship, with the severity of DED being associated with anxiety and depression symptoms.¹⁹ While treating DED may alleviate depression symptoms and vice versa, the use of SSRIs as depression treatment can worsen DED, making the management of these comorbidities more complex.¹⁹ Nonetheless, potential therapeutic targets may offer future treatments for depression associated with DED. In conclusion, the researchers raised awareness that the interplay between DED and depression significantly impacts patients' well-being, emphasizing the importance of collaboration between psychiatrists and ophthalmologists in managing individuals with DED.¹⁹

The study conducted a comprehensive evaluation of oral and ocular symptoms in primary Sjögren's syndrome (pSS) patients, comparing them to non-SS sicca controls and healthy subjects without sicca complaints.¹⁹ Subjective complaints and objective findings, such as saliva and tear secretion rates, tear film stability, ocular surface staining, and candida counts, were recorded. Participating researchers included dentists and rheumatologists. The pSS patients experienced higher levels of subjective and objective dryness than both control groups, with significant correlations between oral and ocular dryness in the pSS group. These findings suggest that an interdisciplinary evaluation of patients with xerostomia and xerophthalmia can aid in patient care and help differentiate between pSS and non-SS sicca patients.¹⁹ Collaboration with a dentist or rheumatologist may be advised if a patient has dryness in the mouth and eye.²⁰

Summary

Dry eye disease is a common condition that affects the tear film. The tear film is a thin layer of fluid that coats the eye and helps to keep it moist and healthy. When the tear film is not properly produced or distributed, it can cause symptoms such as eye dryness, irritation, and blurred vision. The pharmacy team is poised to support eye care in patients. Perfluorohexyloctane is a new treatment option for DED that the FDA recently approved. It forms a protective layer on the eye to reduce tear evaporation. Perfluorohexyloctane has been shown to be safe and effective in clinical trials. It is well-tolerated by most patients and has a favorable safety profile. In addition to medical treatment, there are lifestyle changes that can help manage DED. It is also important to note that patients with DED may have an increased risk of depression; therefore, collaboration with the primary care physician or a psychiatrist might be warranted.

Course Test

1. Dry eye is a disease of the

- a. optic disc.
- b. retina.
- c. eye's surface.
- d. eyelids.

2. In addition to ocular discomfort and visual impairment, dry eye disease can cause

- a. inflammation of the ocular surface.
- b. retinal detachment.
- c. glaucoma.
- d. floaters.

3. In the United States, _____ is a risk factor for dry eye disease.

- a. male gender
- b. female gender
- c. race
- d. education

4. Perfluorohexyloctane is applied to the eye to help

- a. reduce tear evaporation.
- b. increase tear production.
- c. lubricate the eye.
- d. remove debris from the eye.

5. Which of the following is the most common side effect of perfluorohexyloctane?

- a. Stained cornea
- b. Dryness
- c. Irritation
- d. Blurred vision

6. Mild dry eye disease treatment includes lifestyle modifications to reduce the symptoms, including

- a. avoiding the use of sunglasses.
- b. using eyelash serums.
- c. purposely blinking more often when viewing digital screens.
- d. avoiding the use of humidifiers.

7. How long should you wait after using perfluorohexyloctane before reinserting contact lenses?

- a. 15 minutes
- b. 30 minutes
- c. 1 hour
- d. 2 hours

8. For more severe cases, prescription eye drops, such as _____, may be used to reduce inflammation and increase tear production.

- a. perfluorohexyloctane
- b. tetracyclines
- c. corticosteroids
- d. cyclosporine or lifitegrast

9. What is the current prognosis for dry eye disease?

- a. It is typically a chronic condition that can be managed but not cured.
- b. It is a temporary condition that usually goes away if the patient changes geographical location.
- c. It is a chronic dry eye condition that always has clinical signs.
- d. It is always caused by a neuropathic condition that cannot be treated.

10. _____ is the leading cause of evaporative dry eye disease.

- a. Glaucoma
- b. Blurred vision
- c. Meibomian gland dysfunction
- d. Retinal detachment

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